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PATENT

Attorney Docket No. 13447US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Sreedhara Alavattam et al.

Serial No.: 10/750,475

Art Unit: 1653

Filed: December 31, 2003

Examiner: Roy, Gargi

Customer No. 24116

Confirmation No. 9857

For: BIODEGRADABLE MICROPARTICLES THAT STABILIZE AND CONTROL THE
RELEASE OF PROTEIN

Mail Stop Amendment
Commissioner for Patents
PO BOX 1450
Alexandria, VA 22313-1450

Dear Sir:

DECLARATION OF RICHARD S. BRODY – 37 C.F.R. § 1.132

I, Richard S. Brody, 3539 Olentangy Boulevard, Columbus, OH, 43214, United States
of America, hereby declare:

1. I received a B.A in Chemistry from Cornell University in 1972 and a Ph.D in
Chemistry from Harvard University in 1978. I was a Postdoctoral Fellow in
Biochemistry at The Ohio State University from 1979 – 1981.
2. My broad experience encompasses work in development of formulations for protein
stabilization, development of procedures for purification of therapeutic proteins,
development of peptide maps for therapeutic proteins, and purification, sequence
analysis, and identification of unknown proteins.

3. I am currently a Research Leader for Biochemistry at Battelle Memorial Institute in Columbus, Ohio. I have authored or coauthored ten scientific papers, and have been inventor or co-inventor of twelve US patents.

4. That I have read and understand the present Patent Application having Serial No. 10/750,475; and the related Office Action, mailed August 25, 2005.

5. I am a co-inventor of the present application together with Sreedhara Alavattam. Presently claims 1 through 28 stand rejected as anticipated by the reference Zhu et al. (hereinafter Zhu), the reference by Morlock et al. (hereinafter Morlock) and the reference Wakeman et al. (hereinafter Wakeman), all cited and discussed in the Official Action.

My first comments relate to claims rejected with the Zhu reference. I hereby state that it is my professional opinion that the remaining amended claims (or claims dependent on amended claims) 1, 3-4, 11, 22, 25-28 rejected on the basis of Zhu are differentiated from Zhu in that these claims all have the limitation of a surfactant coating that is not present in Zhu. Zhu makes no reference to the use of a surfactant to coat the stabilized protein mixture.

My second comments relate to Morlock. It is my professional opinion that the remaining amended claims (or claims dependent on amended claims) 1, 3-5, 7-9, 11, 21, and 23-28 rejected on the basis of Morlock are differentiated from Morlock in that the claims all require a surfactant coating on the stabilized protein mixture which is then encapsulated by a biodegradable polymer. Morlock in contrast teaches the formation of a protein that is encapsulated in a biodegradable polymer and then coated with polyvinyl alcohol.

Additionally, the Official Action has characterized polyvinyl alcohol in Wakeman as an anionic surfactant. It is my professional opinion that polyvinyl alcohol is an alcohol, is not ionic, and does not possess the properties of an anionic surfactant. It is respectfully suggested that Wakeman does discuss the use of an anionic surfactant with a polyvinyl alcohol, but does not suggest that polyvinyl alcohol is anionic.

Finally, the polyvinyl alcohol in Morlock, even if it were a surfactant, never coats the protein, but instead coats the outer surface of a biodegradable polymer that has already encapsulated the protein. Accordingly the references appear to be clearly different from the claimed invention.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: December 27, 2005

By: Richard S. Brody
Richard S. Brody